FORM APPROVED
OMB NO. 0579-0213
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# GUIDANCE DOCUMENT FOR APPLICATION FOR LABORATORY REGISTRATION FOR POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

## INTRODUCTION

The "Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (Public Law 107-188; June 12, 2002) requires that the United States improve its ability to prevent, prepare for, and respond to bioterrorism and other public health emergencies. It necessitates that individuals possessing, using or transferring agents or toxins deemed a severe threat to public, animal or plant health, or to animal or plant products, notify either the Secretary of the Department of Health and Human Services (HHS) or the Secretary of the Department of Agriculture (USDA). Subsequent to enactment of this law, requirements for possession, use, and transfer of select agents and toxins were published by HHS (42 CFR 73) and by USDA (9 CFR 121 and 7 CFR 331).

Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the Secretary, HHS, and to the Animal and Plant Health Inspection Service (APHIS) by the Secretary, USDA. In order to minimize the reporting burden to the public, APHIS and CDC have developed a common reporting form for this data collection. This form (APHIS/CDC Form 1) is designed to assist entities in complying with this legal obligation.

This application package is for entities required to register to possess, use, or transfer select agents under Public Law 104-132 and its implementing regulation (42 CFR 73 - *Select Biological Agents and Toxins*; 7 CFR 331 - *Possession, Use, and Transfer of Biological Agents and Toxins*; and 9 CFR 121- *Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins*). An entity[1] is required by regulation (42 CFR 73, 9 CFR 121, and 7 CFR 331) to register with either APHIS or CDC if they wish to use, possess, or transfer select agents or toxins. The entity should assign a Responsible Official (RO) to assume responsibility for providing application information to the appropriate agency. The agency that the RO should contact is determined by the type of select agent or toxin that they possess. For HHS agents, the RO should contact CDC (telephone: 404-498-2255; facsimile 404-498-2265). For HHS/USDA overlap agents, the RO should contact either APHIS or the CDC. For USDA agents, the RO should contact APHIS (telephone: 301-734-5960; facsimile: 301-734-3652). A listing of HHS select agents and toxins is available at http://www.cdc.gov/od/sap. A listing of USDA select agents and toxins is available at http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

## RESPONSIBLE OFFICIAL

The regulation requires that a RO of the entity be identified, that the entity has facilities meeting the requirements to work safely with select agent(s), that only authorized personnel have access to select agents, and that registered entities keep records of select agents transferred to and from their facilities. The RO must be approved based on a security risk assessment by The Attorney General (Public Act 212(e)(3)), be familiar with the regulations (7 CFR 331, 9 CFR 121, and 42 CFR 73), and have the authority and responsibility to ensure that the requirements of the appropriate regulations are met.

An entity may also designate an alternate RO in cases where extended absences or other circumstances warrant acting for the RO in his or her absence. The alternate RO must meet all of the qualifications for a RO. We recommend that the RO and alternate RO are biosafety officers or senior management officials of the entity, or both. Although we understand that some entities have limited staff, we recommend that the RO not be an individual actually using, working with, or transferring or receiving the select agents and toxins to minimize potential conflicts of interest.

The purpose of the RO and alternate RO is to ensure management oversight of the implementation of the select agent regulations and to provide an established point of contact for the entity. He or she is the designated individual responsible for all activities relating to the handling or transfer of select agents under the regulation. The RO and alternate RO must review and sign the Certification form (Section 2), and will be the person(s) contacted if APHIS or CDC have questions concerning the application or other matters related to the regulation. The RO or alternate RO should consult with others (e.g., engineering support services, principal investigators) as necessary to obtain the information required for this application. The RO or his or her alternate RO are also responsible for notifying APHIS or CDC of any changes to the registration, such as modifications to authorized laboratory personnel, changes in currently registered laboratories, additional new laboratories that require registration, or other changes to this application.

**REGISTRATION**

Entities wishing to register must submit an application to APHIS or CDC for review:

1. To apply for a certificate of registration that covers only HHS select agents or toxins, an entity must submit the application package to CDC.
2. To apply for a certificate of registration that covers only USDA select agents or toxins, an entity must submit the application package to APHIS.
3. To apply for a certificate of registration that does not cover only HHS select agents or toxins (i.e., covers at least one overlap select agent and/or toxin, or covers any combination of HHS select agents and/or toxins and USDA select agents and/or toxins), an entity must submit the application package to APHIS or CDC, but not both.

Before you complete this application, please read these documents carefully to determine whether your entity is required to register. Please review the exemptions and exclusions requirements set forth in 7 CFR 331, and 9 CFR 121, and 42 CFR 73.

**FOR HHS SELECT AGENTS, SEND COMPLETED FORMS TO CDC:**

Centers for Disease Control and Prevention
Select Agent Program
1600 Clifton Road, NE
Mail Stop E-79
Atlanta, GA 30333

**FOR USDA SELECT AGENTS, SEND COMPLETED FORMS TO APHIS:**

Agricultural Select Agent Program
4700 River Road, Unit 2
Mailstop 22, Cubicle 1A07
Riverdale, MD 20737

**FOR HHS/USDA OVERLAP AGENTS, SEND COMPLETED FORMS TO:**

Either APHIS or CDC at the addresses listed above

The entity should also perform a facility risk assessment (see 42 CFR 73.11-12, 9 CFR 121.11-12, and 7 CFR 331.11-12) that is based on the requirements for handling that agent to ensure that the facility meets those requirements. If information supplied in the application package indicates that the entity is properly equipped and capable of handling select agents and toxins, APHIS or CDC may issue a registration certificate to the entity. The registration is valid for a period up to three years. All entities will be subject to inspection during the three-year registration period.

If an entity's application fails to document that the entity is properly equipped and capable of work with select agents, or if the application is incomplete, the entity will not be registered. APHIS or CDC will inform the entity of

[1] Entity as defined by HHS/CDC and USDA/APHIS means any government agency (Federal, State, or local), university, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

problems with the application by contacting the designated RO. Upon resolution of the problem, the entity may again seek registration. Allow at least 8 weeks for processing. Submission of an incomplete application will result in a significant delay in processing the application. Send all supporting documentation on 8½" by 11" paper in black and white, not color. Currently, there is no fee for registration for select agents and toxins.

**CONTENTS OF THIS APPLICATION PACKAGE**

1. Application overview and instructions for registration of entity
2. Forms to be completed by applicants

**NOTE:** This guidance document and form are also available at http://www.cdc.gov/od/sap or http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

**INSTRUCTIONS FOR REGISTRATION OF ENTITY**

Forms to be completed by all applicants:

(1) Section 1- Entity, RO, and alternate RO information. If more than one alternate RO has been identified, additional Section 1 and 2 should be completed, as appropriate.

(2) Section 2 - Certification and Signature form. This form must be signed by the RO and the alternate RO for the institution.

(3) Section 3 - Indicate each select agent or toxin which is currently in possession, use or in storage at the entity, or those that you anticipate working with in the near future (e.g., within 6 months).

(4) Section 4A - For each of the select agents the entity plans to use, list the following information on a separate line: the select agent(s); the characteristics of each select agent (e.g., viable, genomic, recombinant material, use in small or large animals, or large scale), the building and room number(s) where select agent(s) will be used and stored, and, the facility risk assessment based on the requirements for the type of activities conducted in each of the rooms. In the "facility agent ID" column indicate any identification used to identify a specific agent or toxin or derivatives of these (i.e., EEE-p102 to identify a modified strain of EEE that is unique to your laboratory).

Example 1. An entity needs to register one principal investigator (e.g., Dr. Jane Doe will be working with viable *Bacillus anthracis* in Bldg A, Room 2 at BSL-2; large scale production of *Bacillus anthracis* in Bldg A, Room 5 at BSL3; and *Bacillus anthracis* in small mammals in Bldg B, Room 200 at ABSL2). Storage of the agents will be in the same locations where the work will be conducted.

| AGENTS/ACTIVITIES TO BE CONDUCTED AT THE ENTITY | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Facility Agent ID | Viable | Genomic material | Recombinant DNA | Small Animal | Large Animal | Large Scale | Toxin | Laboratory Area | | Storage Area | | Laboratory Safety Level | Principal Investigator |
| | | | | | | | | | Bldg | Room | Bldg | Room | | |
| **SELECT AGENT** | **INDICATE WITH AN "X" FOR EACH AGENT AS APPROPRIATE** | | | | | | | | | | | | | |
| *Bacillus anthracis* | | X | | | | | | | A | 2 | A | 2 | BSL2 | Dr. Jane Doe |
| *Bacillus anthracis* | | | | | | | X | | A | 5 | A | 5 | BSL3 | Dr. Jane Doe |
| *Bacillus anthracis* | | | | | X | | | | B | 200 | B | 200 | ABSL2 | Dr. Jane Doe |

Example 2. An entity needs to register three principal investigators (e.g., Dr. John Smith will be working with recombinant Ebola in Bldg 15, Room 100 at NIHBL-4; Dr. Mary Johnson will be working with botulinum toxins in Bldg 3A, Room 1000 under 29 CFR 1910.1450 conditions; and Dr. Tony Small will be working with viable *Francisella tularensis* in Bldg 4, Room 300 at BSL3 and viable *Brucella melitensis* in the same room). Storage of the agents will be in the same locations where the work will be conducted.

| AGENTS/ACTIVITIES TO BE CONDUCTED AT THE ENTITY | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Facility Agent ID | Viable | Genomic material | Recombinant DNA | Small Animal | Large Animal | Large Scale | Toxin | Laboratory Area | | Storage Area | | LaboratorySafety Level | Principal Investigator |
| | | | | | | | | | Bldg | Room | Bldg | Room | | |
| **SELECT AGENT** | **INDICATE WITH AN "X" FOR EACH AGENT AS APPROPRIATE** | | | | | | | | | | | | | |
| Ebola virus | | | | X | | | | | 15 | 100 | 15 | 100 | NIHBL4 | Dr. John Smith |
| Botulinum toxin | | | | | | | | X | 3A | 1000 | 3A | 1000 | 29 CFR | Dr. Mary Johnson |
| *Francisella tularensis* | | X | | | | | | | 4 | 300 | 4 | 300 | BSL3 | Dr. Tony Small |
| *Brucella melitensis* | | X | | | | | | | 4 | 300 | 4 | 300 | BSL3 | Dr. Tony Small |

(5) Section 4B - All RO's should complete this section by providing the following information for the RO, alternate RO, owners of the entity, as well as *each* person who is authorized to have access to select agents in the institution. The information provided in this section must correspond to that presented in Section 3 and Table 4A or it will delay processing the application. The name (including the middle initial), the date of birth and address, (including zip code) for individuals listed on this table should be identical to that given on the Form FD-961 submitted to CJIS for each individual. To request additions to or deletions from this list of individuals, submit this page to the same agency that you filed your original application with (APHIS or CDC). The first and last name of each individual should correspond exactly to the information submitted to the Attorney General. NOTE: Table 4B relates to the Principal Investigator (PI) who is accountable for the work listed on the Table 4A. The "supervising principal investigator" field on Table 4B refers to the individual who is supervising all activities associated with select agents and toxins in the specified rooms. Thus, the PI listed in Table 4B may not be the direct supervisor of the individual. For example, facilities, support and administrative personnel have superiors they report to, but the "supervising PI" listed in Table 4B refers to the person whose work is registered with the APHIS or CDC.

**Submitting security risk assessment (SRA) information.** A notification will be given to the entity with the unique Department of Justice (DOJ) identifying number for each individual listed on the Table 4B or amended 4B. The RO should then forward to each individual their unique DOJ identifying number. The individual should complete the FBI form (FD-961), including their unique identifying number in block 17. The individual should follow all of the FBI instructions (http://www.fbi.gov/hq/cjisd/takingfps.html) for submitting fingerprints and then mail the FD-961 form and fingerprint cards as one package directly to the Federal Bureau of Investigation (FBI), Criminal Justice Information Services Division (CJIS). Specific guidance on the process is available at http://www.cdc.gov/od/sap, http://www.aphis.usda.gov/programs/ag_selectagent/index.html, or http://www.fbi.gov/terrorinfo/bioterrorfd961.htm.

Example (Section 4B). John Johnson will be working with viable *Bacillus anthracis* in Bldg A, Room 2 at BSL-2 in Dr. Jane Doe's laboratory. Although Dr. Jane Doe is not his immediate supervisor, her name should be listed because she is responsible for the agent in this laboratory.

| Last Name | First Name | Middle Initial | Date of Birth | Home Address (No P.O. boxes) | Supervising Principal Investigator (PI's, RO's, and owners leave this column blank) | Agent(s)/ Toxins | Laboratory Building | Laboratory Room | Job Title |
|---|---|---|---|---|---|---|---|---|---|
| Doe | Jane | A. | 1/1/61 | 123 Street City, ST 01234 | | *Bacillus anthracis* | A | 2 | Principal Investigator |
| Johnson | John | D. | 1/2/60 | 456 Lane City, ST 01234 | Doe | *Bacillus anthracis* | A | 2 | Laboratorian |

(6) Section 5A and 5B - All RO's should complete these sections for *each* of the principal investigators and each laboratory at their institution. Complete Sections 5C through 5G as appropriate for the agents in use for each principal investigator.

(7) Section 6 is to be completed by all entities that have biosafety level 4 or animal biosafety level 4 laboratories. Sections 6A and 6B - All RO's should complete these sections for *each* of the principal investigators at their institution. Complete Sections 6C through 6F as appropriate for the agents in use for each principal investigator.

**FACILITY RISK ASSESSMENTS AND SAFETY LEVELS: REQUIREMENTS FOR HANDLING SELECT AGENTS**

All entities using select agents should base their facility risk assessments on the applicable sections of the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), *NIH Guidelines for Research Involving Recombinant DNA* (*NIH Guidelines*), 29 CFR 1910.1450, or other required assessment materials.

- Laboratories working with live select agent viruses, bacteria, or fungi should base their facility risk assessments on the BMBL. Use the BMBL to determine the appropriate Biosafety Level (BSL) for the various types of work to be conducted with each of the select agents.
- Laboratories working with recombinant DNA or genetic elements should base their facility assessment on the *NIH Guidelines* to determine the recommended Biosafety Level (BSL) for the type of work to be conducted with each of the select agents. Institutions using recombinant DNA for large animal studies or in large scale production should base their facility risk assessments on the *NIH Guidelines*, as there are no corresponding sections in the BMBL.
- Laboratories working with select agent toxins should meet the requirements of 29 CFR 1910.1450, *Occupational Exposure to Hazardous Chemicals in Laboratories*, and the toxin guidelines contained in Appendix I of the BMBL. If the entity is also working with intact select toxin-producing organisms or recombinant DNA encoding for select agent toxins, the laboratory should base its facility risk assessments on the BMBL and/or *NIH Guidelines* in addition to 29 CFR 1910.1450. Certain conditions may exclude select agent toxins from the requirements of this regulation (see 42 CFR 73.3(e)(1) and 42 CFR 73.4(e)(1)).
- Distributors of toxins in which the toxins are only handled in sealed containers should meet the requirements 29 CFR 1910.1200, *Hazard Communication*.

**ADDITIONAL MATERIALS YOU MAY NEED:**

(1) *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). The BMBL is available on the internet at http://www.cdc.gov/od/sap. An errata sheet for the most current edition of the BMBL is available at the internet website: http://www.cdc.gov/od/sap.

(2) *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines*). The *NIH Guidelines* are available at http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html.

(3) 29 CFR 1910.1450 - *Occupational Exposure to Hazardous Chemicals in the Laboratory.* Available on the Internet at http://www.osha.gov/ or from the U.S. Government Printing Office (phone 202-512-1800).

(4) 29 CFR 1200 - *Hazard Communication.* Available on the Internet at http://www.osha.gov/ or from the U.S. Government Printing Office (phone 202-512-1800).

(5) Additional information and clarification is available at http://www.cdc.gov/od/sap and http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

**HOW TO AMEND YOUR REGISTRATION**

To add, delete or change information on your registration, complete the relevant portion of the registration application package and return to the appropriate agency. These forms are available on the internet at http://www.cdc.gov/od/sap and http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

**HOW TO DESIGNATE A DIFFERENT OR ALTERNATE RO**

In the event that an entity loses the services of its Responsible Official, an entity may continue to possess or use select agents or toxins only if it appoints as the Responsible Official another individual who has been approved by the HHS Secretary or Administrator following a security risk assessment by the Attorney General and who meets the requirements of this part. To designate a different RO or an alternate RO, the current RO must mail or fax to the appropriate agency a signed statement on official entity facility letterhead requesting such changes. In addition, the new RO or alternate RO must submit Sections 1 and 2. The alternate RO must meet all of the qualifications for a RO. See additional details outlined in the section above entitled *Responsible Official*.

**OBTAINING EXTRA COPIES OF THIS FORM**

To obtain additional copies of this form, contact CDC at (404) 498-2255 or APHIS at (301) 734-5960. It is also permissible to photocopy the originals contained in this application package if additional copies are needed. This

application and guidance document is also available on the CDC Web site at http://www.cdc.gov, and http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

**HOW THE INFORMATION IN THIS APPLICATION PACKAGE WILL BE USED**

Each section of the application package is designed to obtain specific information required under 42 CFR 73, 7 CFR 331, and 9 CFR 121.

**PUBLIC REPORTING BURDEN**

The public reporting burden of this collection of information for the requirements of this application request is estimated to be 3.75 hours. An agency may not conduct, nor is an individual required to respond to, information collection unless a current valid OMB control number has been issued. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, ATTN: PRA (0920-0576), MS D-24, Atlanta, Georgia 30333.

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EXP DATE 01/31/2006

# APPLICATION FOR LABORATORY REGISTRATION FOR POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

Read all instructions carefully before completing the application. Answer all items completely. Type or print in ink on 8 ½" by 11" paper. All documentation must be in black and white, not color. The application must be signed or it will not be processed. For HHS agents, submit document to: Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE, Mailstop E-79, Atlanta, GA 30333. For HHS/USDA overlap agents submit the form to either APHIS or CDC. For USDA agents, submit document to: Agricultural Select Agent Program, 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07, Riverdale, MD 20737.

## SECTION 1 – ENTITY INFORMATION (TO BE COMPLETED BY ALL RO'S)

Before completing the application, read all instructions carefully. Give complete answers to all items. Type or print in ink.

This application is: ☐ A new registration ☐ A renewal of an existing registration ☐ An amendment to an existing registration

| Current entity registration number(s) (*if applying for amendment or renewal*) | Date |
|---|---|
| | |

Legal name of entity

| Address (NOT a post office box) | City | State | Zip Code |
|---|---|---|---|
| | | | |

Type of entity: ☐ Academic (Private) ☐ Academic (State) ☐ Government ☐ Commercial (Profit) ☐ Private (Non-Profit)

| Name of Responsible Official (RO): | Last Name | First Name | Middle Name |
|---|---|---|---|
| | | | |

| Date of birth | Title of Responsible Official (e.g., biosafety officer): |
|---|---|
| | |

| Business Telephone | Business FAX | Business E-mail |
|---|---|---|
| | | |

| Business Address (NOT a post office box) | City | State | Zip Code |
|---|---|---|---|
| | | | |

| Name of Alternate Responsible Official (ARO): | Last Name | First Name | Middle Name |
|---|---|---|---|
| | | | |

| Date of birth | Title of Alternate Responsible Official (e.g., biosafety officer): |
|---|---|
| | |

| Business Telephone | Business FAX | Business E-mail |
|---|---|---|
| | | |

| Business Address (NOT a post office box) | City | State | Zip Code |
|---|---|---|---|
| | | | |

Has this entity previously been registered with the Select Agent Program? Yes No
if yes, then provide Select Agent Program registration number and expiration date:

## SECTION 2 – CERTIFICATION AND SIGNATURE
**(TO BE COMPLETED BY ALL RO'S AND ALTERNATE RO'S)**

I hereby certify that I have been designated as the Responsible Official or the Alternate Responsible Official for the institution/organization listed above, that I am authorized to bind the institution/organization, and that the information supplied in this registration package is, to the best of my knowledge, accurate and truthful. The institution/organization listed above meets the requirements specified in 7 CFR 331, 9 CFR 121, and 42 CFR 73 is equipped and capable of safely and securely handling the agent(s) and will use or transfer these agents solely for purposes authorized by 7 CFR 331, 9 CFR 121, and 42 CFR 73.

I understand that a false statement on any part of this agreement or failure to comply with the provisions of the applicable regulations may result in the immediate revocation of this entity's registration as described in 7 CFR 331, 9 CFR 121, and 42 CFR 73 could result in a civil fine of up to $500,000 for each violation, or if criminally prosecuted a criminal fine or imprisonment for up to five years, or both for each violation. (7 U.S.C. 8401; 18 U.S.C. 175, 175b, 1001, 3559, 3571; 42 U.S.C. 264, 271).

| _____ | _____ | _____ |
|---|---|---|
| Responsible Official Signature | Date | RO Name (typed or printed) |
| _____ | _____ | _____ |
| Alternate Responsible Official Signature | Date | Alternate RO Name (typed or printed) |

Date:_____

**SECTION 3 – SELECT AGENTS USED, POSSESSED, OR TRANSFERRED BY ENTITY**
**(TO BE COMPLETED BY ALL RO'S)**

Indicate each select agent or toxin that your entity intends to register by placing an "X" in the box for each agent or toxin (check one or more as appropriate). Items that are exempt from registration should not be listed on this form.

**HHS SELECT AGENTS AND TOXINS**

- ☐ Cercopithecine herpesvirus 1 (Herpes B virus)
- ☐ *Coccidioides posadasii*
- ☐ Crimean-Congo haemorrhagic fever virus
- ☐ Ebola viruses
- ☐ Lassa fever virus
- ☐ Marburg virus
- ☐ Monkeypox virus
- ☐ Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
- ☐ *Rickettsia prowazekii*
- ☐ *Rickettsia rickettsii*
- South American haemorrhagic fever viruses
  - ☐ Junin
  - ☐ Machupo
  - ☐ Sabia
  - ☐ Flexal
  - ☐ Guanarito
- Tick-borne encephalitis complex (flavi) viruses
  - ☐ Central European tick-borne encephalitis
  - ☐ Far Eastern tick-borne encephalitis
  - ☐ Russian spring and summer encephalitis
  - ☐ Kyasanur forest disease
  - ☐ Omsk hemorrhagic fever
- ☐ Variola major virus (Smallpox virus)
- ☐ Variola minor virus (Alastrim)
- ☐ *Yersinia pestis*
- ☐ Abrin
- ☐ Conotoxins
- ☐ Diacetoxyscirpenol
- ☐ Ricin
- ☐ Saxitoxin
- ☐ Shiga-like ribosome inactivating proteins
- ☐ Tetrodotoxin

**USDA SELECT AGENTS AND TOXINS**

- ☐ African swine fever virus
- ☐ African horse sickness virus
- ☐ Akabane virus
- ☐ Avian influenza virus (highly pathogenic)
- ☐ Blue tongue virus (Exotic)
- ☐ Bovine spongiform encephalopathy agent
- ☐ Camel pox virus
- ☐ Classical swine fever virus
- ☐ *Cowdria ruminantium* (Heartwater)
- ☐ Foot and mouth disease virus
- ☐ Goat pox virus
- ☐ Japanese encephalitis virus
- ☐ Lumpy skin disease virus
- ☐ Malignant catarrhal fever (Alcelaphine herpesvirus type 1)
- ☐ Menangle virus
- ☐ *Mycoplasma capricolum*/ M.F38/*M. mycoides capri*
- ☐ *Mycoplasma mycoides mycoides*
- ☐ Newcastle disease virus (velogenic)
- ☐ Peste Des Petits Ruminants virus
- ☐ Rinderpest virus
- ☐ Sheep pox virus
- ☐ Swine vesicular disease virus
- ☐ Vesicular stomatitis virus (Exotic)

**USDA PLANT PATHOGENS**

- ☐ *Liberobacter africanus*
- ☐ *Liberobacter asiaticus*
- ☐ *Peronosclerospora philippinensis*
- ☐ *Ralstonia solanacearum* race 3, biovar 2
- ☐ *Schlerophthora rayssiae* var *zeae*
- ☐ *Synchytrium endobioticum*
- ☐ *Xanthomonas oryzae*
- ☐ *Xylella fastidiosa* (citrus variegated chlorosis strain)

**OVERLAP SELECT AGENTS AND TOXINS**

- ☐ *Bacillus anthracis*
- ☐ *Brucella abortus*
- ☐ *Brucella melitensis*
- ☐ *Brucella suis*
- ☐ *Burkholderia mallei* (formerly *Pseudomonas mallei*)
- ☐ *Burkholderia pseudomallei* (formerly *Pseudomonas pseudomallei*)
- ☐ Botulinum neurotoxin producing species of *Clostridium*
- ☐ *Coccidioides immitis*
- ☐ *Coxiella burnetii*
- ☐ Eastern equine encephalitis virus
- ☐ *Francisella tularensis*
- ☐ Hendra virus
- ☐ Nipah Virus
- ☐ Rift Valley fever virus
- ☐ Venezuelan equine encephalitis virus
- ☐ Botulinum neurotoxin
- ☐ *Clostridium perfringens* epsilon toxin
- ☐ Shigatoxin
- ☐ Staphylococcal enterotoxin
- ☐ T-2 toxin

Date:_____

## SECTION 4 – SELECT AGENT INFORMATION
**(TO BE COMPLETED BY ALL RO'S)**

## SECTION 4A. BIOSAFETY AND LABORATORY INFORMATION ON SELECT AGENTS

All applicants must complete this table. For each Principal Investigator (or Chief Scientist) and laboratory or storage room list each select agent or toxin by type (viable, genomic material, small animal, etc.) on a separate line. Failure to complete this table in detail will delay processing of your application.

| Agent/Toxin name | Viable | Genomic Material | Recombinant DNA | Small Animal | Large Animal | Large Scale | Toxin | Laboratory Area | | Storage Area | | Laboratory Safety Level* | Principal Investigator |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Bldg | Room | Bldg | Room | | |
| | INDICATE WITH AN "X" FOR EACH AGENT AS APPROPRIATE | | | | | | | | | | | | |
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*Biosafety Level 2=BSL2 Animal Biosafety Level 2=ABSL2 rDNA BSL2=NIHBL2 rDNA Large Animal BSL2=NIH BL2N rDNA Large Scale BSL2=NIH BL2-LS
Biosafety Level 3=BSL3 Animal Biosafety Level 3=ABSL3 rDNA BSL3=NIHBL3 rDNA Large Animal BSL3=NIH BL3N rDNA Large Scale BSL3=NIH BL3-LS
Biosafety Level 4=BSL4 Animal Biosafety Level 4=ABSL4 rDNA BSL4=NIHBL4 rDNA Large Animal BSL4=NIH BL4N rDNA Large Scale BSL4=NIH BL4-LS

Toxin= 29 CFR 1910.1450, 29 CFR 1910.1200 and BMBL Appendix I

Registration number (if applicable) _____

## SECTION 4B – AUTHORIZED PERSONNEL WORKING WITH SELECT AGENTS

Provide the following information for the RO, alternate RO, owners of the entity, as well as *each* person who is authorized to have access to select agents and toxins at the entity. The information provided in this section must correspond to that presented in Section 3 and 4A or it will delay processing the application. The name (including the middle initial) and the date of birth and address (including zip code) for individuals listed on this table should be identical to that given on the Form FD-961 submitted to CJIS for each individual. To request additions to or deletions from this list of individuals, submit this page to the agency that you filed your original application (APHIS or CDC). The first and last name of each individual should correspond exactly to the information submitted to the Attorney General.

| Last Name | First Name | Middle Initial | Date of Birth | Home Address (No P.O. boxes) | Principal Investigator (PI's, RO's, and owners leave this column blank) | Agent(s)/Toxins | Laboratory Building | Laboratory Room | Job Title |
|---|---|---|---|---|---|---|---|---|---|
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I certify that the individuals listed above have a legitimate need for access to select agents and toxins in the laboratories listed above, and that each individual has the training and skills to safely work with these agents or toxins.

RO Signature:_____ Date: _____

Principal investigator: _____ Laboratory building: _____ Laboratory room number(s): _____ Date: _____

## SECTION 5 – LABORATORY INFORMATION
**(COMPLETED BY EACH PRINCIPAL INVESTIGATOR AND APPROVED BY THE RO)**

Provide the following information for each Principal Investigator working with select agents and toxins at your entity. Make additional copies of this section of the form as needed. Each principal investigator should complete questions 1 through 87, as appropriate for *each* laboratory room where select agents are used or stored. Incomplete answers will delay processing the application. In the "facility agent ID" column indicate any identification used to identify a specific agent or toxin or derivatives of these (i.e., EEE-p102 to identify a modified strain of EEE that is unique to your laboratory).

## SECTION 5A – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR

*Include a current resume or Curriculum Vitae from the principal investigator.*

1. Name of individual responsible for the laboratory (e.g., principal investigator): _____
2. Provide the following information for each agent(s) worked with or stored in the laboratory building(s) and room(s):

| AGENT/TOXIN NAME | STRAIN DESIGNATION | DATE ACQUIRED (list N/A if not acquired) | ADDRESS OF FACILITY FROM WHICH THE AGENT/TOXIN WAS ACQUIRED (Include registration number if applicable) | FACILITY AGENT I.D. | SOURCE OF ISOLATE | | | UNIQUE DIAGNOSTIC CHARACTERISTICS | REFERENCE FOR PUBLISHED SEQUENCE INFORMATION (GenBank accession number, journal articles, etc.) |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | Clinical | Environmental | Other (explain) | | |
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Principal investigator: _____ Laboratory building: _____ Laboratory room number(s): _____ Date: _____

**SECTION 5A – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR (Continued)**

Make additional copies of this section of the form as needed for *each* laboratory room for each principal investigator at your entity. Each principal investigator should complete questions 3 through 87, as appropriate for *each* laboratory where select agents are used or stored. If all laboratories with the same biosafety level under the control of one principal investigator meet the same criteria, then list all laboratory rooms and submit only one form. Include a floor plan for each laboratory where agents or toxins are to be used or stored (for all biosafety levels).

3. Floor plan(s) include:
   - a. Sink locations ☐ Yes ☐ No
   - b. Eyewash locations ☐ Yes ☐ No
   - c. Biological safety cabinet (BSC) locations ☐ Yes ☐ No
   - d. Fume hood locations ☐ Yes ☐ No
   - e. HVAC supply and exhaust locations ☐ Yes ☐ No
   - f. Freezer/refrigerator locations ☐ Yes ☐ No
   - g. Other large equipment locations (incubators, centrifuges, etc) ☐ Yes ☐ No
4. Provide a description of the HVAC system (*check all that are appropriate*):
   - a. ☐ Single-pass ☐ Re-circulated
   - b. ☐ Dedicated exhaust ☐ Shared exhaust
   - c. ☐ Constant air volume ☐ Variable air volume
   - d. ☐ Redundant exhaust fans
   - e. ☐ Emergency power back-up
5. Provide information on the biological safety cabinets in use (attach additional sheets if needed):
   - a. Class of cabinet: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐II, B2 ☐ III
   - b. Biological safety cabinet connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating
   - c. Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain):_____
   - d. Does user verify air inflow during BSC use? ☐ Yes ☐ No

6. **NOTE**: If your entity has a BSL-4 or ABSL-4 laboratory, then skip to Section 6 and complete Sections 6A and 6B, and any other sections that are applicable to your entity.

7. BSL-3 laboratory registration must answer the following:
   - a. Entry into the lab is through a double set of lockable self-closing doors: ☐ Yes ☐ No
   - b. Each laboratory room has a hands-free sink: ☐ Yes ☐ No
   - c. An eyewash station is readily available inside the laboratory: ☐ Yes ☐ No
   - d. There is an autoclave or other verified or approved method for decontamination within the laboratory: ☐ Yes ☐ No
   - e. If no autoclave in the BSL-3 laboratory, describe waste handling protocols to be used by the laboratory personnel: _____ _____
   - f. Laboratory exhaust is re-circulated to other areas of the facility: ☐ Yes ☐ No
   - g. The laboratory is maintained at negative air pressure to provide directional air into the laboratory: ☐ Yes ☐ No
   - h. A visual system is provided for laboratory personnel to monitor directional air before entry and during use of the laboratory: ☐ Yes ☐ No
   - i. An alarm system is provided to warn laboratory personnel of exhaust system failure: ☐ Yes ☐ No
   - j. HEPA filtration of all exhaust air is in place: ☐ Yes ☐ No

Principal investigator: _____ Laboratory building: _____ Laboratory room number(s): _____ Date: _____

8. ABSL-2 laboratory registration must include the following:
   a. Animal laboratories are separated from open and unrestricted areas: ☐ Yes ☐ No
   b. Animal laboratory exhaust is re-circulated to other areas of the facility: ☐ Yes ☐ No
   c. The animal laboratory is maintained at negative air pressure to provide directional air into the animal laboratory: ☐ Yes ☐ No
   d. There is an autoclave in the laboratory: ☐ Yes ☐ No
   e. External doors are self-closing, self-locking, and open inward: ☐ Yes ☐ No
   f. Cage washing is: ☐ Manual ☐ With a mechanical cage washer
   g. The cage washing area is shown on attached floor plan: ☐ Yes ☐ No
   h. Each animal room where infected animals are kept contains a hand-washing sink: ☐ Yes ☐ No
   i. If floor drains are provided, the traps are always filled with an appropriate disinfectant: ☐ Yes ☐ No

9. ABSL-3 laboratory registration must include the following:
   a. Animal laboratories are separated from open and unrestricted areas: ☐ Yes ☐ No
   b. Entry into the animal lab is through a double set of lockable self-closing doors: ☐ Yes ☐ No
   c. External doors are self-closing, self-locking, and open inward: ☐ Yes ☐ No
   d. Each animal room contains a hands-free hand washing sink: ☐ Yes ☐ No
   e. Animal laboratory exhaust is re-circulated to other areas of the entity: ☐ Yes ☐ No
   f. The animal laboratory is maintained at negative air pressure to provide directional air into the animal laboratory: ☐ Yes ☐ No
   g. A visual system is provided for laboratory personnel to monitor directional air before entry and during use of the animal laboratory: ☐ Yes ☐ No
   h. An alarm system is provided to warn laboratory personnel of exhaust system failure: ☐ Yes ☐ No
   i. HEPA filtration of all exhaust air is present: ☐ Yes ☐ No
   j. There is an autoclave in the laboratory: ☐ Yes ☐ No
   k. Cage washing is with a mechanical cage washer: ☐ Yes ☐ No
   l. Cage washing area is shown on the floor plans: ☐ Yes ☐ No
   m. Animal waste treated (carcasses, sewage, bedding, etc.) before disposal ☐ Yes ☐ No
      If yes describe treatment method: _____
   n. If floor drains are provided, the traps are always filled with an appropriate disinfectant: ☐ Yes ☐ No

**ALL LABORATORIES MUST ANSWER THE FOLLOWING:**

10. Laboratory is currently operational: ☐ Yes ☐ No
    If no, date of anticipated completion of laboratory: _____
11. Appropriate personal protective equipment is used: ☐ Yes ☐ No
12. Vacuum lines contain HEPA filters: Yes No No vacuum lines are used
13. Each laboratory using select agents has an agent-specific, site-specific biosafety manual: ☐ Yes ☐ No
14. A medical surveillance system is in place for laboratory personnel using select agents: ☐ Yes ☐ No
15. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director: ☐ Yes ☐ No
16. A sharps policy is in place for this laboratory (or laboratories): ☐ Yes ☐ No
17. A site-specific emergency operations plan is available for this laboratory: ☐ Yes ☐ No

18. An Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with select agents at this facility? ☐ Yes ☐No

    a. If yes, has IBC approved the work proposed in this application: Yes No

    b. The facility has been inspected by USDA, FDA, CLIA, DoE, DoD or others: Yes No

    c. If yes, then give agency and date of last inspection(s): _____

19. Briefly state (no more than a paragraph) the objectives of the work with the select agent(s), including a description of the methodologies or laboratory procedures that will be used. State if any host-vector systems will be used. Specify whether work will involve live agents and recombinant DNA:

_____

_____

_____

_____

_____

**SECTION 5B – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR (TRAINING AND SECURITY)**

20. Training:

    a. Site specific security and safety training is provided to individuals with access to areas where select agents are handled or stored: ☐ Yes ☐ No

    b. Is provided prior to individuals beginning to work with select agents: ☐ Yes ☐ No

    c. Is provided: ☐ Annually ☐ Biannually ☐ Other (specify frequency): _____

    d. Written records of individuals trained are kept: ☐ Yes ☐ No

    e. Personnel demonstrate proficiency in laboratory procedures prior to working with select agents: ☐ Yes ☐ No

    f. Provide a brief description of what is included in the training program:

    _____

    _____

21. Provide a brief explanation of the system in place to detect loss or theft of select agent(s):

_____

_____

    a. Individual responsible for inventory of select agent(s):

    _____

    b. How often is the inventory record reconciled?

    _____

    c. How is access to the inventory log limited?

    _____

    d. Inventory tracking includes the following information (list):

    _____

    _____

22. There is a site-specific security plan for each of the laboratories listed above in Section 5A (number 2): ☐ Yes ☐ No

    a. Building with select agents has self-closing doors: ☐ Yes ☐ No

b. Means to limit access to buildings with laboratories with select agents:
☐ Guard station at the entity entrance
☐ Card access system or locks
☐ Security alarm system in the laboratory building

☐ Other (describe): _____

_____

c. Means to limit access to laboratories with select agents once inside the building:
☐ Door to laboratory is locked

☐ Guard station at the building entrance
☐ Card access system or locks
☐ Security alarm system in the laboratory

☐ Other (describe): _____

d. Means to limit access to select agents once inside the laboratory:
☐ Locked incubators, refrigerators, freezers, etc.
☐ Security alarm system that directly monitors the laboratory
☐ Other (describe): _____

e. Means to limit access to select agents in storage:
☐ Storage area door locked
☐ Lock boxes
☐ Security alarm system that directly monitors the laboratory
☐ Other (describe): _____

f. Means to monitor unauthorized entry into the laboratory where select agents are used or stored:
☐ Electronic logs of card access system entries are reviewed for unusual activity
☐ Manual sign in and out logs are kept and monitored

☐ Video camera surveillance
☐ Other (describe): _____

g. The laboratory is secured when no one is present during regular working hours: ☐ Yes ☐ No

h. Individuals not directly involved in research activities have access to select agents: ☐ Yes ☐ No

If yes, please explain:_____

i. Non-laboratory personnel (visitors, including janitorial and entity maintenance personnel) have access to the laboratory with select agents: ☐ Yes ☐ No

If yes, are they allowed into the laboratory unescorted? ☐ Yes ☐ No

j. Provide additional details regarding how the entity limits access to the laboratories where select agents are being manipulated and stored to only authorized and qualified persons (add additional sheets as necessary):

_____
_____

**SECTION 5C –TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH INFECTIOUS AGENTS**

23. Provide an estimate of the maximum quantities (e.g., number of petri dishes or total volume of liquid media) and concentration of each organisms grown at a given time (e.g., 2 - 250 ml flasks of $10^5$ cfu/ml):

_____

24. All cultures, stock and other regulated wastes are decontaminated before disposal by an approved decontamination method: ☐ Yes ☐ No

a. If yes, describe method:_____

Principal investigator: _____ Laboratory building: _____ Laboratory room number(s): _____ Date: _____

**SECTION 5D – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH RECOMBINANT DNA OR GENOMIC MATERIAL**

25. The entity has an Institutional Biosafety Committee that has approved work with recombinant DNA or has approval pending: ☐ Yes ☐ No
26. The biosafety level listed in Section 4A for this laboratory meets NIH guidelines: ☐ Yes ☐ No
27. Will you be possessing, using or transferring the following:
    a. Nucleic acids that can produce infectious forms of any of the select agent viruses. ☐ Yes ☐ No
    b. Recombinant nucleic acids that encode for the functional form(s) of any select toxins if the nucleic acids:
        1) can be expressed in vivo or in vitro. ☐ Yes ☐ No
        2) are in a vector or recombinant host genome and can be expressed in vivo or in vitro. ☐ Yes ☐ No
    c. Select agent viruses, bacteria, fungi, and toxins that have been genetically modified. ☐ Yes ☐ No
28. Are you intending to conduct the following experiments:
    a. Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture. ☐ Yes ☐ No
    b. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an $LD_{50}$ < 100 ng/kg body weight. ☐ Yes ☐ No
29. Provide a brief description of the recombinant constructs and any associated expression control elements, including what the recombinant DNA encodes for, if known: _____
30. Give an estimate of range of length of recombinant DNA to be used: _____

**SECTION 5E – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH SMALL ANIMALS**

31. List species of small animals that will be used: _____
32. Describe route of infection: _____
33. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.):
    a. If yes, describe method:_____
34. The entity requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this entity: ☐ Yes ☐ No
    a. If yes, the proposed work with select agents in small animals has been approved by the IACUC: ☐ Yes ☐ No
35. The laboratory is accredited by AAALAC: ☐ Yes ☐ No
    a. If yes, give accreditation date: _____

**SECTION 5F – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH LARGE ANIMALS**

36. List species of large animals that will be used: _____
37. Describe route of infection: _____
38. Carcass of animals are disposed in a manner to preclude their use as food for human beings or animals: ☐ Yes ☐ No
39. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐ Yes ☐ No
    a. If yes, give method:_____
40. Carcass of animals are disposed of on site: ☐ Yes ☐ No
41. The entity requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this entity: ☐ Yes ☐ No
    a. If yes, the proposed work with select agents in large animals has been approved by the IACUC: ☐ Yes ☐ No

42. The laboratory is accredited by AAALAC: ☐ Yes ☐ No

    a. If yes, give accreditation date: _____

**SECTION 5G – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH TOXINS**

43. A Chemical Hygiene Plan is available for the laboratory using toxins: ☐ Yes ☐ No

44. Maximum quantity of each toxin under the control of the principal investigator at a given time: _____

45. Form of toxins used: ☐ Liquid ☐ Lyophilized ☐ Not Applicable-Storage Only

46. The toxin is produced by live agent at the entity: ☐ Yes ☐ No

    a. If yes, provide a brief description of procedures used (include an estimate of the maximum quantities grown at a given time): _____

47. Dilution procedures and other manipulations of the concentrated toxins are:

    a. Conducted in ☐ Fume hood ☐ Biological safety cabinet ☐ Not Applicable-Storage Only

        1) If a fume hood or biosafety cabinet is used, certification is conducted:
        ☐ Annually ☐ Biannually ☐ Other (describe): _____

    b. Work is conducted with two knowledgeable people present: ☐ Yes ☐ No

48. A hazard sign is posted on the door when toxins are present: ☐ Yes ☐ No

**SECTION 6A – BSL4/ABSL4 LABORATORIES ONLY: TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR**

*NOTE: All entities must also complete Section 5A, Questions 1 and 2, above (APHIS/CDC Form 1)*

49. All entities must answer the following questions for each BSL-4 laboratory for each Principal Investigator:

    a. Activities conducted under BSL-4 containment (check all that apply):

        ☐ Research ☐ Diagnostic ☐ Large scale production ☐ Small animal ☐ Large animal

        ☐ Recombinant DNA ☐ Other (give description):_____

    b. How many separate BSL-4 laboratories are you registering for select agent work?

        ☐ 1 laboratory ☐ 2 laboratories ☐ 3 or more laboratories

    c. Are these laboratories currently registered with the CDC Select Agent Program? Yes ☐ No

    d. Are these BSL-4 laboratories currently operational (presently conducting BSL-4 work)? ☐ Yes ☐ No

        If no, date of anticipated completion of laboratories: _____

    e. What type of BSL-4 laboratories are you registering?

        ☐ Protective suit laboratory ☐ Stand alone Class III cabinet laboratory

        ☐ Protective suit laboratory with associated Class III cabinet

50. Include a floor plan for each BSL-4 laboratory, Class III cabinet laboratory, or ABSL-4 laboratory where select agents are to be used or stored.

    Floor plan(s) must include:

    a. Sink locations ☐ Yes ☐ No

    b. Eyewash locations ☐ Yes ☐ No

    c. Laboratory furniture locations (including bench work) ☐ Yes ☐ No

    d. Biosafety cabinet (BSC) locations ☐ Yes ☐ No

    e. Fume hood locations ☐ Yes ☐ No ☐ N/A: No fume hoods

    f. HVAC supply and exhaust locations ☐ Yes ☐ No

g. Freezer/refrigerator locations (include LN2 storage) ☐ Yes ☐ No

h. Other large equipment locations (e.g., incubators, centrifuges) ☐ Yes ☐ No

51. Provide information on the biosafety cabinets in use (attach additional sheets if needed):

a. Class of cabinet: ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐II, B2 ☐ Class III

b. Biosafety cabinet connection to the HVAC system: ☐ Hard ducted ☐ Thimble ☐ Re-circulating

c. Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain):_____

52. Provide a description of the BSL-4 HVAC system (*check all that are appropriate*):

a. ☐ Single-pass

b. ☐ Dedicated exhaust

c. ☐ Constant air volume ☐ Variable air volume

d. ☐ Redundant exhaust fans

e. ☐ Emergency power back-up

53. Vacuum lines contain HEPA filters: ☐ Yes ☐ No ☐ No vacuum lines are used

54. A medical surveillance system is in place for laboratory personnel using select agents for toxins: ☐ Yes ☐ No

55. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director: ☐ Yes ☐ No

56. A sharps policy is in place for this laboratory: ☐ Yes ☐ No

57. A site-specific emergency operations plan is available for this laboratory: ☐ Yes ☐ No

58. An Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with select agents at this entity: ☐ Yes ☐ No

a. If yes, has IBC approved the work proposed in this application: ☐ Yes ☐ No

b. The laboratory has been inspected by USDA, FDA, CLIA, DoE, DoD or others: ☐ Yes ☐ No

c. If yes, then give agency and date of last inspection(s): _____

59. Briefly state (no more than a paragraph) the objectives of the work with the select agents or toxins, including a description of the methodologies or laboratory procedures that will be used. State if any host-vector systems will be used. Specify whether work will involve live agents and recombinant DNA:_____

_____
_____
_____
_____
_____

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60. Provide <u>general facility and safety information</u> for the BSL-4 laboratory facility (ies) you are registering by answering the questions in this section. Use separate sheets if necessary.

a. BSL-4 laboratory design and operational procedures are documented and re-verified annually: ☐ Yes ☐ No

b. A specific BSL-4 facility operations manual has been prepared: ☐ Yes ☐ No

c. All standard BSL-4 microbiological practices are followed: ☐ Yes ☐ No

d. There is a mandatory daily inspection of the containment parameters for the BSL-4 laboratory area(s) and critical life support systems: ☐ Yes ☐ No

e. Walls, floors, and ceilings of the BSL-4 laboratory rooms are sealed. All penetrations into the laboratory are sealed: ☐ Yes ☐ No

f. The HVAC system is dedicated and is not re-circulated: ☐ Yes ☐ No

g. There is a visual and auditory alarm system provided to alert facility workers to system malfunctions and/or failures of containment parameters: ☐ Yes ☐ No

h. Entry to the laboratory is through a double set of lockable, self-closing doors: ☐ Yes ☐ No

i. Each protective suit or cabinet laboratory room has a hands-free sink: ☐ Yes ☐ No

j. There is a double door autoclave for decontamination of materials from the suit lab and/or the Class III cabinet and cabinet room: ☐ Yes ☐ No

k. A visual pressure differential monitoring system is provided at the clean change room for laboratory personnel to verify directional air before entry into the BSL-4 laboratory: ☐ Yes ☐ No

l. Differential pressures/directional airflow between adjacent areas is monitored and alarmed (visually and audibly) to indicate system failure: ☐ Yes ☐ No

m. Double HEPA filtration of all suit area, decontamination shower, decontamination airlock and Class III cabinet exhaust air is in place: ☐ Yes ☐ No

n. Single HEPA filtration of all suit area, decontamination shower, decontamination airlock and Class III cabinet supply air is in place: ☐ Yes ☐ No

o. Describe method utilized for decontamination of BSL-4 area(s):

_____

_____

p. Inactivation of organisms and materials removed from BSL-4 containment is accomplished by what methods?

☐ Irradiation ☐ Chemical disinfection ☐ Autoclaving ☐ Other

Describe:_____

_____

q. Inactivation of materials removed from BSL-4 containment is verified: ☐ Yes ☐ No

Describe:_____

---

**Facilities registering a laboratory containing a Class III cabinet, must answer question 61. Facilities wishing to register protective suit laboratories and <u>suit laboratories with associated Class III cabinets must also answer question 62</u>.**

61. Entities registering a **stand alone Class III cabinet laboratory** must verify the following items:

a. Entry to the laboratory housing the Class III cabinet is through a double set of lockable, self-closing doors: ☐ Yes ☐ No

b. Inner and outer change rooms are separated by a shower for personnel entering and leaving the cabinet room: ☐ Yes ☐ No

c. There is a double-door (pass-through) autoclave, dunk tank, fumigation chamber, or ventilated anteroom for passing materials, supplies, or equipment into or out of the cabinet room: ☐ Yes ☐ No

d. Walls, floors, and ceilings of the cabinet room(s) are sealed and all penetrations into the cabinet room(s) are sealed: ☐ Yes ☐ No

e. Floors are seamless and coved: ☐ Yes ☐ No

f. All drains in the cabinet room(s), inner change room(s), and autoclave chambers connect directly to an appropriate liquid waste decontamination system: ☐ Yes ☐ No

g. Sewer vents and other service lines contain HEPA filters: ☐ Yes ☐ No

h. Bench tops are seamless or sealed surfaces that are impervious to water and resistant to moderate heat and organic solvents, acids, alkalis, and other decontaminant chemicals: ☐ Yes ☐ No

i. Laboratory furniture is capable of supporting anticipated loads and uses and is covered with a non-fabric material that can be easily decontaminated: ☐ Yes ☐ No

j. A hands-free sink is located in the cabinet room(s) near the door and in the inner and outer change room: ☐ Yes ☐ No

k. If a central vacuum system is present, it serves only the cabinet room(s) and is HEPA filter protected, and liquid and gas services to the cabinet room are protected by backflow prevention devices: ☐ Yes ☐ No

l. Any windows are break resistant and sealed: ☐ Yes ☐ No

m. Double-door autoclaves are provided for decontamination of materials removed from the Class III cabinet and the cabinet room. These autoclaves are interlocked so that the outside door can only be opened after the sterilization cycle is complete: ☐ Yes ☐ No

n. Pass-through dunk tanks, fumigation chambers, or equivalent decontamination methods are provided so that materials and equipment that cannot be decontaminated in the autoclave can be safely removed from both the Class III biological safety cabinet(s) and the cabinet room(s): ☐ Yes ☐ No

o. All HEPA filters are tested and certified annually: ☐ Yes ☐ No

p. An HVAC monitoring system is provided to avoid pressurization of the laboratory and is alarmed to warn laboratorians of exhaust system failure: ☐ Yes ☐ No

q. There is HEPA filtration of all supply and exhaust air from the cabinet room(s), inner change room(s), and anteroom(s): ☐ Yes ☐ No

r. The Class III cabinet is directly connected to the exhaust system with HEPA filtration on the supply and double HEPA filtration on the exhaust: ☐ Yes ☐ No

s. Appropriate communication systems are provided between the laboratory and external personnel (intercom, phone, fax, and computer): ☐ Yes ☐ No

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62. Entities registering a **protective suit laboratory or a protective suit laboratory with associated Class III cabinet registration** must verify the following items (**suit laboratories with associated Class III cabinets must also answer question 61**):

a. Entry into the area(s) where work is performed with BSL-4 agents [suit room(s)] is through a series of changing and decontamination areas separated by airtight doors: ☐ Yes ☐ No

b. Inner and outer change rooms are separated by a personal shower: ☐ Yes ☐ No

c. A chemical shower is provided for decontaminating the outer surface of the protective suit: ☐ Yes ☐ No

d. A breathing air system is provided with redundant compressors, backup storage tanks, HEPA filtration protection, and alarm monitoring in the event of failure: ☐ Yes ☐ No

e. All penetrations into containment shell (walls, floors, and ceilings) of the suit area(s), chemical shower(s), and airlock(s) are sealed: ☐ Yes ☐ No

f. Daily inspections of the containment parameters and life support systems are performed, completed and documented before laboratory work begins: ☐ Yes ☐ No

g. A double-door, interlocked autoclave is provided for decontaminating waste materials removed from the suit area(s): ☐ Yes ☐ No

h. A dunk tank, fumigation chamber, or ventilated airlock to pass materials, supplies, or equipment into or out of the suit area(s): ☐ Yes ☐ No

i. Bench tops are seamless surfaces that are impervious to water and resistant to moderate heat and organic solvents, acids, alkalis, and other decontaminant chemicals: ☐ Yes ☐ No

j. Laboratory furniture is capable of supporting anticipated loads and uses and is covered with a non-fabric material that can be easily decontaminated: ☐ Yes ☐ No

k. A hands-free sink is located in the suit area(s): ☐ Yes ☐ No

l. If a central vacuum system is present, it serves only the suit area(s) and is protected by HEPA filtration: ☐ Yes ☐ No

m. Liquid and gas services to the suit area(s) are protected by backflow devices: ☐ Yes ☐ No

n. Inner and outer doors to chemical showers and airlocks are interlocked to prevent both doors from being opened at the same time: ☐ Yes ☐ No

o. Any windows are break resistant and sealed: ☐ Yes ☐ No

p. All drains in the suit area(s), chemical shower(s), and autoclave chambers connect directly to an appropriate liquid waste decontamination system: ☐ Yes ☐ No

q. An HVAC monitoring system is provided to avoid pressurization of the laboratory and is alarmed to warn laboratorians in the event of exhaust system failure: ☐ Yes ☐ No

r. Redundant exhaust fans are installed: ☐ Yes ☐ No

s. All HEPA filters are tested and certified annually: ☐ Yes ☐ No

t. HVAC supply to the suit area(s), chemical shower(s), and airlock(s) is HEPA filtered: ☐ Yes ☐ No

u. HVAC exhaust from the suit area(s), chemical shower(s), and airlock(s) is double HEPA filtered with the HEPA filters in series: ☐ Yes ☐ No

v. Appropriate communication systems are provided between the laboratory and external personnel (intercom, phone, fax, and computer): ☐ Yes ☐ No

w. Emergency lighting and emergency communications systems are provided for the BSL-4 areas: ☐ Yes ☐ No

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63. Entities registering an **ABSL-4 laboratory** must provide the following information. Entities registering a **stand alone Class III cabinet** for housing animals infected with biosafety level 4 agents, or other ABSL-4 use must complete **question 61** above. Entities registering a **protective suit laboratory** housing animals infected with Biosafety level 4 agents must complete **question 62 as well as the following**:

a. List animal models in use for ABSL-4 experiments: _____

_____

b. ABSL-4 laboratory room(s) designations: _____

c. Specific procedures have been developed for handling animals under ABSL-4 conditions in the Class III cabinet or protective suit laboratories being registered: ☐ Yes ☐ No

d. All appropriate special policies and procedures are approved by the Institutional Animal Care and Use Committee: ☐ Yes ☐ No

e. Aerosol experiments are conducted in this ABSL-4 laboratories: ☐ Yes ☐ No

f. Describe how animals are housed under ABSL-4 conditions (add additional sheets as necessary):

_____

_____

g. Cage washing is with a mechanical cage washer: ☐ Yes ☐ No

h. Cage washing area is shown on the floor plans: ☐ Yes ☐ No

i. Waste (e.g., carcasses, sewage, bedding, etc.) is sterilized before disposal: ☐ Yes ☐ No

Describe treatment method: _____

j. Method of disposal of treated carcasses: ☐ Incineration ☐ Rendering ☐ Chemical decomposition

☐ Other (*describe*): _____

k. If floor drains are provided, the traps are always filled with an appropriate disinfectant: ☐ Yes ☐ No

l. Appropriate personal protective equipment is used: ☐ Yes ☐ No

m. Personnel assigned to work with infected animals work in pairs: ☐ Yes ☐ No

Principal investigator: _____ Laboratory building: _____ Laboratory room number(s): _____ Date: _____

**SECTION 6B – BSL4/ABSL4 LABORATORIES ONLY: TO BE COMPLETED BY ALL ENTITIES (TRAINING AND SECURITY)**

64. Training:

a. Site-specific security training is provided to individuals with access to areas where BSL-4 select agents are handled or stored: ☐ Yes ☐ No

b. Site-specific safety training is provided to individuals with access to areas where BSL-4 select agents are handled or stored: ☐ Yes ☐ No

c. A biosafety manual has been prepared that indicates special hazards associated with the BSL-4 agents in use and laboratory personnel are required to read and follow these practices and procedures: ☐ Yes ☐ No

d. Training is provided to laboratory personnel prior to beginning work with BSL-4 select agents: ☐ Yes ☐ No

e. Training is provided: ☐ Annually ☐ Biannually ☐ Other (specify frequency): _____

f. Written records of individuals trained are kept: ☐ Yes ☐ No

g. Personnel are required to demonstrate proficiency in laboratory procedures prior to working with BSL-4 select agents: ☐ Yes ☐ No

h. Please provide a brief description of the individual training program for BSL-4 laboratory personnel (attach additional sheets if necessary):

_____

_____

65. Security:

a. Provide a brief explanation of the system in place to detect loss or theft of select agent(s):

_____

_____

_____

b. All viable BSL-4 agents are stored within the BSL-4 containment area: ☐ Yes ☐ No

If no, then provide list of rooms where BSL4 agents are stored: _____

c. Storage areas within BSL-4 containment are under surveillance: ☐ Yes ☐ No

d. Describe type of surveillance: _____

66. There is a site-specific security plan for each of the BSL-4 laboratories listed above: ☐ Yes ☐ No

a. Only persons whose presence in the BSL-4 laboratory facility or individual laboratory rooms is required for program or support purposes are authorized to enter: ☐ Yes ☐ No

b. Access to the laboratory is controlled by locked doors: ☐ Yes ☐ No

c. A log book indicating date and time of entry and exit of all personnel to and from the BSL-4 containment area is maintained: ☐ Yes ☐ No

d. Indicate means of limiting access to buildings with BSL-4 laboratories using select agents:
☐ Guard station at the entity entrance
☐ Card access system or locks
☐ Other (describe): _____

e. Indicate means of limiting access to select agents once inside the building:
☐ Door to laboratory is locked
☐ Guard station at the building entrance
☐ Card access system or locks
☐ Other (describe): _____

f. Means to limit access to select agents once inside the laboratory:
☐ Locked incubators, refrigerators, freezers, etc.
☐ Other (describe): _____

g. Means to limit access to select agents in storage:
☐ Storage area door locked
☐ Lock boxes
☐ Other (describe): _____

h. Means to monitor unauthorized entry into the BSl-4 laboratory where select agents are used or stored:
☐ Electronic logs of card access system entries are reviewed for unusual activity
☐ Manual sign in and out logs are kept and monitored
☐ Camera surveillance (e.g., CCTV)
☐ Security alarm system that directly monitors the laboratory
☐ Other (describe): _____

i. The laboratory is secured when no one is present during regular working hours: ☐ Yes ☐ No

j. The laboratory is secured when no one is present after regular working hours: ☐ Yes ☐ No

k. Total number of personnel with access to BSL-4 area during operations:_____

l. Individuals not directly involved in research activities have access to select agents: ☐ Yes ☐ No

If yes, please explain: _____

m. Non-laboratory personnel (visitors, including janitorial and facility maintenance personnel) have access to the laboratory with select agents: ☐ Yes ☐ No

If yes, are they allowed into the laboratory unescorted? ☐ Yes ☐ No

If yes, please explain: _____

n. Describe how the entity limits access to the laboratories where select agents are being manipulated and stored to only authorized and qualified persons:

_____

_____

## SECTION 6C – BSL4/ABSL4 LABORATORIES ONLY: TO BE COMPLETED BY ENTITIES WORKING WITH INFECTIOUS AGENTS

67. Provide an estimate of the maximum quantities (e.g., number of petri dishes or total volume of liquid media) and concentration of organisms grown at a given time (e.g., 2 - 250 ml flasks of $10^5$ cfu/ml):

_____

68. All cultures, stock and other regulated wastes are decontaminated before disposal by an approved sterilization method: ☐ Yes ☐ No

If yes, describe method:_____

## SECTION 6D – BSL4/ABSL4 LABORATORIES ONLY: TO BE COMPLETED BY ENTITIES WORKING WITH RECOMBINANT DNA OR GENOMIC MATERIAL

69. This laboratory meets NIH guidelines for research involving recombinant DNA molecules: ☐ Yes ☐ No

70. Will you possess, use or transfer the following:

a. Nucleic acids that can produce infectious forms of any of the select agent viruses. ☐ Yes ☐ No

b. Recombinant nucleic acids that encode for the functional form(s) of any select toxins if the nucleic acids:

1) can be expressed in vivo or in vitro. ☐ Yes ☐ No

2) are in a vector or recombinant host genome and can be expressed in vivo or in vitro. ☐ Yes ☐ No

c. Select agent viruses, bacteria, fungi, and toxins that have been genetically modified. ☐ Yes ☐ No

71. Do you intend to conduct the following experiments:

a. Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture. ☐ Yes ☐ No

b. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an $LD_{50}$ < 100 ng/kg body weight. ☐ Yes ☐ No

72. Provide a brief description of the recombinant constructs and any associated expression control elements, including what the recombinant DNA encodes for, if known: _____

73. Give an estimate of range of length of recombinant DNA to be used: _____

**SECTION 6E – BSL4/ABSL4 LABORATORIES ONLY: TO BE COMPLETED BY ENTITIES WORKING WITH SMALL ANIMALS**

74. List species of small animals that will be used: _____

75. Describe route of infection: _____

76. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐ Yes ☐ No

If yes, describe method: _____

77. The entity requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this laboratory: ☐ Yes ☐ No

a. If yes, the proposed work with select agents in small animals has been approved by the IACUC: ☐ Yes ☐ No

b. The laboratory space is accredited by AAALAC: ☐ Yes ☐ No

c. If yes, give inspection date: _____

**SECTION 6F – BSL4/ABSL4 LABORATORIES ONLY: TO BE COMPLETED BY ENTITIES WORKING WITH LARGE ANIMALS**

78. List species of large animals that will be used: _____

a. Describe route of infection: _____

b. Carcass of animals are disposed in a manner to preclude their use as food for human beings or animals: ☐ Yes ☐ No

c. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐ Yes ☐ No

If yes, give method:_____

79. Carcass of animals are disposed on site: ☐ Yes ☐ No

80. The entity requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this entity: ☐ Yes ☐ No

If yes, the proposed work with select agents in large animals has been approved by the IACUC: ☐ Yes ☐ No

81. The laboratory space is accredited by AAALAC: ☐ Yes ☐ No

**SECTION 6G – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH TOXINS**

82. A Chemical Hygiene Plan is available for the laboratory using toxins: ☐ Yes ☐ No

83. Maximum quantity of each toxin under the control of the principal investigator at a given time: _____

84. Form of toxins used: ☐ Liquid ☐ Lyophilized ☐ Not Applicable-Storage Only

85. The toxin is produced by live agent at the entity: ☐ Yes ☐ No

If yes, provide a brief description of procedures used (include an estimate of the maximum quantities grown at a given time): _____

86. Dilution procedures and other manipulations of the concentrated toxins are:

a. Conducted in ☐ Fume hood ☐ Biological safety cabinet ☐ Not Applicable-Storage Only

1) If a fume hood or biosafety cabinet is used, certification is conducted:
☐ Annually ☐ Biannually ☐ Other (describe): _____

b. Work is conducted with two knowledgeable people present: ☐ Yes ☐ No

87. A hazard sign is posted on the door when toxins are present: ☐ Yes ☐ No